UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF TEXAS CORPUS CHRISTI DIVISION

Clerk, U.S. District Court Southern District of Texas FILED

MAR 22 2017

David J. Bradley, Clerk of Court

UNITED STATES OF AMERICA

v.

Ordered Amended per BJE

ELIAS TREVINO, JR. 3/27/17

aka "A MAN: ELI"

VANESA GONZALES

aka VANESA TREVINO

aka "A WOMAN: VANE"

§

CRIMINAL NUMBER

C - 17 - 189

INDICTMENT

THE GRAND JURY CHARGES THAT:

A. Introduction

At all times material to this Indictment:

- 1. ELIAS TREVINO and VANESSA GONZALES were the owners and operators of X2Zero. X2Zero was a retailer of products claiming to be dietary supplements with two physical locations in Corpus Christi, Texas. Products were also sold online through the website stores.x2zero.com, and through an eBay online storefront. The websites x2zero.com, pierdeya.com, and 361weightloss.com all redirected web traffic to the website stores.x2zero.com.
- 2. The United States Customs and Border Protection ("CBP"), and Immigration and Customs Enforcement, Homeland Security Investigations ("ICE-HSI"), two agencies within the United States Department of Homeland Security ("DHS"), were the federal agencies responsible for administering and enforcing violations of the laws governing the importation into the United States of goods and merchandise, including drugs, devices, and biological products.

- 3. The FDA was the federal agency charged with the responsibility of protecting the health and safety of the American public by ensuring that drugs sold to the public were safe and effective for their intended uses and bore labeling containing true, complete and accurate information.
- 4. Labeling includes all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers or accompanying such an article. A drug is misbranded if its labeling is false or misleading in any particular, if its labeling fails to bear adequate warnings, or if it is dangerous to health when used in the dosage or manner suggested in the labeling of the product.
- 5. Under federal law, controlled substances were placed into five categories, or schedules, according to their potential for abuse, dependence, and accepted medical use. Schedule II, III, IV, and V, controlled substances required written prescriptions issued for a legitimate medical purpose by a licensed medical practitioner.
- 6. Under federal law only persons or entities registered with the Drug Enforcement Administration (DEA) could import a Schedule IV controlled substance into the United States or be involved in its lawful distribution within the United States.

B. Sibutramine, Phenolphthalein, and Sildenafil

7. Sibutramine, an amphetamine analog pharmacologically similar to other anorectic agents that produce central nervous system stimulation and amphetamine-like effects in humans, was classified as a schedule IV controlled substance.

- 8. In 1997, the FDA approved a prescription drug containing sibutramine under the trade name "Meridia" for the management of obesity. In October 2010, the FDA requested the marketer of Meridia to withdraw the drug from the United States market due to the health risks associated with sibutramine, including an increased risk of heart attack, stroke, and death. On December 21, 2010, at the request of the manufacturer, the FDA withdrew its approval of Meridia. Since the removal of Meridia no drug containing sibutramine has been approved for human use in the United States.
- 9. Phenolphthalein was a component of some over-the-counter laxatives sold in the United States prior to 1999. On January 29, 1999, after it was determined that phenolphthalein was genotoxic in that it can damage or cause mutations to DNA as well as a potential carcinogen in humans, the FDA issued a final rule establishing that phenolphthalein was no longer "generally recognized as safe and effective" and was, therefore, misbranded.
- drug that FDA-approved in 1998 for the treatment of erectile dysfunction. Viagra's required labeling included information regarding indications and usage, dosage and administration, contraindications, warnings, adverse reactions, drug interactions, and a warning that Viagra can cause blood pressure to drop suddenly to an unsafe level if taken with certain other medications. Viagra, and other products containing sildenafil were "drugs" within the meaning of 21 U.S.C. § 321(g)(1)(B) or (C) and prescription drugs within the meaning of 21 U.S.C. § 353(b)(1).

C. The Products

- 11. "Bella Vi AMP'D UP" was sold by X2Zero as an "herbal weight loss supplement" promising "you will lose weight without the use of dangerous chemicals, stimulants and/or additives." Both the label affixed to bottles of "Bella Vi AMP'D UP" and the X2Zero websites listed the ingredients as "Bee Pollen, Senna, Cassia, Chinese Yam, Hawthorn, Fennel Seeds, Bitter Orange, Aloe, Green Tea". "Bella Vi AMP'D UP" was actually a misbranded drug containing sibutramine and phenolphthalein.
- "formulated from a proprietary blend of specialized herbs" and further described as a "powerful combination of natural plants" promising "you will lose weight safely without the use of dangerous chemicals, stimulants and/or additives." Both the label affixed to bottles of "Bella Vi INSANE AMP'D" and the X2Zero websites listed the ingredients as "Bee Pollen, Sickelsenna Seed, Cassia, Seville Orange Flower, Chinese Yam, Aloe, Green Tea, Lotus Leaf, Hawthorn, Honeysuckle, Polyphenols, dietary fiber". "Bella Vi INSANE AMP'D" was actually a misbranded drug containing sibutramine and phenolphthalein.
- 13. "Zeal DynamiZm" was sold by X2Zero as a "complex of herbs that are used to suppress your appetite while feeding your body with essential vitamins and minerals." Both the label affixed to bottles of "Zeal DynamiZm" and the X2Zero websites listed the ingredients as "Natto, Polyporus, Sickel Senna, Wheat Germ." "Zeal DynamiZm" was actually a misbranded drug containing sibutramine.
 - 14. "Vivacious Natural Eruption" was sold by X2Zero as a product

"based on Traditional Chinese Slimming Formulas that use plant extracts, herbs and minerals." The X2Zero websites indicate "Vivacious Natural Eruption" contains "Garcinia Cambogia, Water Plantain, Coffee Pod, Bitter Orange, Nuciferine, Mulberry Leafs", however, the label affixed to bottles of "Vivacious Natural Eruption" list the ingredients as "Garcinia Gummi-gutta, Water Plantain, Java Bean, Bitter Orange, Nymphaea Caerulea, Mulberry Leaf." "Vivacious Natural Eruption" was actually a misbranded drug containing sibutramine.

- 15. "Zeal Xerophagy" was sold by X2Zero as a dietary supplement. Both the label affixed to bottles of "Zeal Xerophagy" and the X2Zero websites listed the ingredients as "Synepherine Hydrocloride, Adlay Seed, Starch, and Seed of Sickel Senna." "Xerophagy" was actually a misbranded drug containing sibutramine.
- 16. "X2Zero Salute" was sold by X2Zero as an "all natural" product containing "natural aphrodisiacs". Both the label affixed to bottles of "X2Zero Salute" and the X2Zero websites listed the ingredients as "Herba Epimedii, Rhodiola Sacra, Genseng, Polygonatum, Desertliving Cistanche, Cinnamon Extract, Amylum." "X2Zero Salute" was actually a misbranded drug containing sildenafil.
- 17. "Zeal ZlimXter" was sold by X2Zero as an "herbal weight loss supplement" promising "you will lose weight without the use of dangerous chemicals, stimulants and/or additives." The X2Zero websites indicate "Zeal ZlimXter" contains "Green Tea, Bitter Orange, Hawthorn, Cassia, and a proprietary blend of Aloe, Senna, Bee Pollen, Fennel Seeds, Chinese Yam", however, the label affixed to bottles of "Zeal ZlimXter" list the ingredients as "Chinese Yam, Fennel

Seed, Senna, Aloe, Salt, Cassia, Hawthorn, Bitter Orange". "Zeal ZlimXter" was actually a misbranded drug containing sibutramine.

18. "Zeal IGNITE" was sold by X2Zero as a product that is "safe without any side effect" and indicated the product contains "zero fillers, zero binders, zero artificial ingredients". Both the label affixed to bottles of "Zeal IGNITE" and the X2Zero websites listed the ingredients as "L-Carnitine, Garcinia Cambogia, Hawthorn Fruit, Cassia Seed, Green Tea, Ginsing, Lotus Leaf, Gelatin." "Zeal IGNITE" was actually a misbranded drug containing phenolphthalein.

D. The Unlawful Conduct COUNT ONE

From on or about October 10, 2013, and continuing until on or about May 31, 2014, in the Corpus Christi Division of the Southern District of Texas and elsewhere within the jurisdiction of the Court, the defendants,

ELIAS TREVINO, JR. aka "A MAN: ELI" and VANESA GONZALES aka VANESA TREVINO aka "A WOMAN: VANE",

each aiding abetting and assisting one another did knowingly and intentionally possess with intent to distribute a controlled substance. This violation involved sibutramine, a Schedule IV controlled substance.

In violation of Title 21, United States Code, Sections 841(a)(1) and 841(b)(2); and Title 18, United States Code, Section 2.

COUNT TWO

From on or about October 10, 2013, and continuing until on or about May 31, 2014, in the Corpus Christi Division of the Southern District of Texas and elsewhere within the jurisdiction of the Court, the defendants,

ELIAS TREVINO, JR. aka "A MAN: ELI" and VANESA GONZALES aka VANESA TREVINO aka "A WOMAN: VANE",

each aiding abetting and assisting one another, acting with the intent to defraud and mislead, caused the introduction and delivery for introduction into interstate commerce a drug that was misbranded as defined in 21 U.S.C. § 352(a), (f)(2) and (j), to wit: "Bella Vi AMP'D UP" capsules containing sibutramine and phenolphthalein falsely labeled as a "herbal weight loss supplement."

In violation of Title 21, United States Code, Sections 331(a) and 333(a)(2); and Title 18, United States Code, Section 2.

COUNT THREE

From on or about October 10, 2013, and continuing until on or about May 30, 2014, in the Corpus Christi Division of the Southern District of Texas and elsewhere within the jurisdiction of the Court, the defendants,

ELIAS TREVINO, JR. aka "A MAN: ELI" and VANESA GONZALES aka VANESA TREVINO aka "A WOMAN: VANE",

each aiding abetting and assisting one another, acting with the intent to defraud and mislead, caused the introduction and delivery for introduction into interstate commerce a drug that was misbranded as defined in 21 U.S.C. § 352(a), (f)(2) and (j), to wit: "Bella Vi INSANE AMP'D" capsules containing sibutramine and phenolphthalein falsely labeled as a "combination of natural plants."

In violation of Title 21, United States Code, Sections 331(a) and 333(a)(2); and Title 18, United States Code, Section 2.

COUNT FOUR

From on or about October 28, 2015, and continuing until on or about August 26, 2016, in the Corpus Christi Division of the Southern District of Texas and elsewhere within the jurisdiction of the Court, the defendants,

ELIAS TREVINO, JR. aka "A MAN: ELI" and VANESA GONZALES aka VANESA TREVINO aka "A WOMAN: VANE",

each aiding abetting and assisting one another, did knowingly and intentionally possess with intent to distribute a controlled substance. This violation involved "Zeal Xerophagy" capsules containing sibutramine, a Schedule IV controlled substance.

In violation of Title 21, United States Code, Sections 841(a)(1) and 841(b)(2); and Title 18, United States Code, Section 2.

COUNT FIVE

From on or about April 15, 2016, and continuing until on or about August 26, 2016, in the Corpus Christi Division of the Southern District of Texas and elsewhere within the jurisdiction of the Court, the defendants,

ELIAS TREVINO, JR. aka "A MAN: ELI" and VANESA GONZALES aka VANESA TREVINO aka "A WOMAN: VANE",

each aiding abetting and assisting one another, did knowingly and intentionally possess with intent to distribute a controlled substance. This violation involved "Zeal ZlimXter" capsules containing sibutramine, a Schedule IV controlled substance.

In violation of Title 21, United States Code, Sections 841(a)(1) and 841(b)(2); and Title 18, United States Code, Section 2.

COUNT SIX

From on or about August 19, 2016, and continuing until on or about August 26, 2016, in the Corpus Christi Division of the Southern District of Texas and elsewhere within the jurisdiction of the Court, the defendants,

ELIAS TREVINO, JR. aka "A MAN: ELI" and VANESA GONZALES aka VANESA TREVINO aka "A WOMAN: VANE",

each aiding abetting and assisting one another, did knowingly and intentionally possess with intent to distribute a controlled substance. This violation involved "Vivacious Natural Eruption" capsules containing sibutramine, a Schedule IV controlled substance.

In violation of Title 21, United States Code, Sections 841(a)(1) and 841(b)(2); and Title 18, United States Code, Section 2.

COUNT SEVEN

On or about March 23, 2015, in the Corpus Christi Division of the Southern District of Texas and elsewhere within the jurisdiction of the Court, the defendants,

ELIAS TREVINO, JR. aka "A MAN: ELI" and VANESA GONZALES aka VANESA TREVINO aka "A WOMAN: VANE",

each aiding abetting and assisting one another, caused the introduction and delivery for introduction into interstate commerce of a drug that was misbranded as defined in 21 U.S.C. § 352(a), (f)(2), and (j), to wit: "Zeal IGNITE" capsules containing phenolphthalein.

In violation of Title 21, United States Code, Sections 331(a) and 333(a)(1); and Title 18, United States Code, Section 2.

COUNT EIGHT

On or about May 21, 2015, in the Corpus Christi Division of the Southern District of Texas and elsewhere within the jurisdiction of the Court, the defendants,

ELIAS TREVINO, JR. aka "A MAN: ELI" and VANESA GONZALES aka VANESA TREVINO aka "A WOMAN: VANE",

each aiding abetting and assisting one another, caused the introduction and delivery for introduction into interstate commerce a drug that was misbranded as defined in 21 U.S.C. § 352(a), (f)(2), and (j), to wit: "Zeal IGNITE" capsules containing phenolphthalein.

In violation of Title 21, United States Code, Sections 331(a) and 333(a)(1); and Title 18, United States Code, Section 2.

COUNT NINE

On or about July 23, 2015, in the Corpus Christi Division of the Southern District of Texas and elsewhere within the jurisdiction of the Court, the defendants,

ELIAS TREVINO, JR. aka "A MAN: ELI" and VANESA GONZALES aka VANESA TREVINO aka "A WOMAN: VANE",

each aiding abetting and assisting one another, caused the introduction and delivery for introduction into interstate commerce of a drug that was misbranded as defined in 21 U.S.C. § 352(a), and (f)(2), to wit: "X2Zero Salute" capsules containing sildenafil.

In violation of Title 21, United States Code, Sections 331(a) and 333(a)(1); and Title 18, United States Code, Section 2.

COUNT TEN

On or about July 23, 2015, in the Corpus Christi Division of the Southern District of Texas and elsewhere within the jurisdiction of the Court, the defendants,

ELIAS TREVINO, JR. aka "A MAN: ELI" and VANESA GONZALES aka VANESA TREVINO aka "A WOMAN: VANE",

each aiding abetting and assisting one another, caused the introduction and delivery for introduction into interstate commerce a drug that was misbranded as defined in 21 U.S.C. § 352(a), (f)(2), and (j), to wit: "Xerophagy" capsules containing sibutramine.

In violation of Title 21, United States Code, Sections 331(a) and 333(a)(1); and Title 18, United States Code, Section 2.

COUNT ELEVEN

On or about October 28, 2015, in the Corpus Christi Division of the Southern District of Texas and elsewhere within the jurisdiction of the Court, the defendants,

ELIAS TREVINO, JR. aka "A MAN: ELI" and VANESA GONZALES aka VANESA TREVINO aka "A WOMAN: VANE",

each aiding abetting and assisting one another, received in interstate commerce, and delivered and proffered delivery thereof for pay and otherwise, a drug that was misbranded as defined in 21 U.S.C. § 352(a), (f)(2), and (j), to wit: "Zeal IGNITE" capsules containing phenolphthalein.

In violation of Title 21, United States Code, Sections 331(c) and 333(a)(1); and Title 18, United States Code, Section 2.

COUNT TWELVE

On or about October 28, 2015, in the Corpus Christi Division of the Southern District of Texas and elsewhere within the jurisdiction of the Court, the defendants,

ELIAS TREVINO, JR. aka "A MAN: ELI" and VANESA GONZALES aka VANESA TREVINO aka "A WOMAN: VANE",

each aiding abetting and assisting one another, received in interstate commerce a drug that was misbranded as defined in 21 U.S.C. § 352(a), (f)(2), and (j), to wit: "Zeal DynamiZm" capsules containing sibutramine, and delivered and proffered delivery thereof for pay and otherwise.

In violation of Title 21, United States Code, Sections 331(c) and 333(a)(1); and Title 18, United States Code, Section 2.

COUNT THIRTEEN

On or about October 28, 2015, in the Corpus Christi Division of the Southern District of Texas and elsewhere within the jurisdiction of the Court, the defendants,

ELIAS TREVINO, JR. aka "A MAN: ELI" and VANESA GONZALES aka VANESA TREVINO aka "A WOMAN: VANE",

each aiding abetting and assisting one another, received in interstate commerce a drug that was misbranded as defined in 21 U.S.C. § 352(a), (f)(2), and (j), to wit: "Vivacious Natural Eruption" capsules containing sibutramine, and delivered and proffered delivery thereof for pay and otherwise.

In violation of Title 21, United States Code, Sections 331(c) and 333(a)(1); and Title 18, United States Code, Section 2.

COUNT FOURTEEN

On or about October 28, 2015, in the Corpus Christi Division of the Southern District of Texas and elsewhere within the jurisdiction of the Court, the defendants,

ELIAS TREVINO , JR. aka "A MAN: ELI" and VANESA GONZALES aka VANESA TREVINO aka "A WOMAN: VANE",

each aiding abetting and assisting one another, received in interstate commerce a drug that was misbranded as defined in 21 U.S.C. § 352(a), and (f)(2), to wit: "X2Zero Salute" capsules containing sildenafil, and delivered and proffered delivery thereof for pay and otherwise.

In violation of Title 21, United States Code, Sections 331(c) and 333(a)(1); and Title 18, United States Code, Section 2.

COUNT FIFTEEN

On or about October 28, 2015, in the Corpus Christi Division of the Southern District of

Texas and elsewhere within the jurisdiction of the Court, the defendants,

ELIAS TREVINO, JR. aka "A MAN: ELI" and VANESA GONZALES aka VANESA TREVINO aka "A WOMAN: VANE",

each aiding abetting and assisting one another, received in interstate commerce a drug that was misbranded as defined in 21 U.S.C. § 352(a), (f)(2), and (j), to wit: "Xerophagy" capsules containing sibutramine, and delivered and proffered delivery thereof for pay and otherwise.

In violation of Title 21, United States Code, Sections 331(c) and 333(a)(1); and Title 18, United States Code, Section 2.

A TRUE BILL: ORIGINAL SIGNATURE ON FILE FOREPERSON OF THE GRAND JURY

ABE MARTINEZ

ACTINGUNITED STATES ATTORNEY

By:

ROBERT D. THORPE, JR. Assistant United States Attorney